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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,850	03/31/2004	Govindan Rajamohan	U 015118-6	5613

7590  
LADAS & PARRY  
26 West 61st Street  
New York, NY 10023

EXAMINER
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WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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03/27/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/814,850	<b>Applicant(s)</b> RAJAMOHAN ET AL.	
	<b>Examiner</b> MALGORZATA A. WALICKA	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Dec. 13, 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 10-25 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 4, 7 and 28 is/are allowed.
- 6) ☐ Claim(s) 1, 2, 5, 6, 8, 9 and 26-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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Non-compliant Amendment of Nov. 27, 2007 and Amendment of Dec. 13, 2007 are acknowledged. Claims 2-9 have been amended, new claims 26-28 have been added. Claims 1-28 are pending in the application. Claims 1-2, 4-9, and new claim 26-28 reading on the elected invention are under examination.

## **DETAILED ACTION**

### **Formal matters**

The examiner acknowledges the Statement of Biological Culture Deposit filed May 7, 2007. The statement as scanned in the PTO records misses BP/4 form of Budapest Treaty on The International Recognition of the Deposit of Microorganisms for the Purposes of the Patent Procedure in case of *E. coli* MTCC05148 and plasmid pOXYSK-2. Please file the missing form.

In response to this objection applicants request that this formal requirement be held in abeyance until the application is otherwise in condition for allowance.

### **Objections**

1. The amendment to pages 4 and 5 of the specification is acknowledged. The last sentence of the amended paragraph of page 4 is not a sentence.

The specification is replete with grammatical errors. A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

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2. Sequence listing contains errors in description of the sequences; see the titles of SEQ ID NOs: 2, 3 and 9.

## **Rejections**

Rejections not repeated below are withdrawn. The examiner wishes to emphasize that:

- 1) claim 3 was inadvertently included in the examination in the Office Action of July 20, 2007 (last action) and was rejected under 35 USC 112 second paragraph and 35 USC 101; the rejection was improper because claim 3 does not belong to the elected invention; and
- 2) rejection under 35 USC 103 made in the last action is withdrawn because it was improper.

## **35 USC 112 first paragraph**

Claims 2, 5, 6 and 8-9 are rejected because they are directed to DNA molecules, and cells transformed with said DNA molecules, that lack proper written description of structure.

The amended claim 2 is directed to the nucleotide sequence comprising nucleotides 13-409 of SEQ ID NO: 2, wherein the sequence encodes SAK-2 protein. The claim is rejected for new matter. Applicants disclosed SEQ ID NO: 2 that is to encode the protein they named SAK-2 protein. Firstly, nowhere in the application

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applicants mention a protein encoded by nucleotides 13-409 of SEQ ID NO: 2. These are 397 nucleotides and are not followed by a stop codon in SEQ ID NO: 2.

Protein named by applicants SAK-2 is the protein presented in Fig. 11 in alignment with its parental protein SAK. SAK-2 in Fig. 11 is five amino acids shorter than SAK i.e., it is 131 amino acid long, and starts with three amino acids: Ala Gly Ala. SAK-2 does not start with Met Lys Gly as required by the nucleotides 13, 14, 15, 16, 17, 18, 19, 20 and 21 of SEQ ID NO: 2. SAK-2 in Fig.11 ends with Glu Lys Lys.

On the other hand, SAK-2 is in the sequence listing identified as SEQ ID NO: 3 that consists of 363 amino acids, starts with Glu Ala Leu and ends with Leu Tyr Ser. Certainly SAK-2 from Fig. 11 is not SAK-2 defined by SEQ ID NO: 3 and none of these amino acid sequences are encoded by nucleotides 13-409 of SEQ ID NO: 2 as required by claim 2.

In conclusion, SAK-2 structure is not described in the disclosure, and for that reason the DNA molecule that encodes SAK- 2 is not disclosed. In result, claims 2, 6, 9 and new claims 26-27 are rejected for lack of written description.

SAK-1 gene that is to be comprised in plasmid pOXYSK-1 and in E. coli having deposition No. 5148 is not claimed by its sequence that is 606 nt long according to Fig. 5. The sequence 606 nt long is identified as SEQ ID NO: 9 in the sequence listing. However, SEQ ID NO: 9 of the sequence listing is described as DNA of *Staphylococcus aureus*, i.e., unmodified DNA of this bacteria and not a man-modified gene.

All these discrepancies are very confusing if one takes into account that the enzyme is known for tens of years and applicants' intention was to modify its N

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terminus, particularly nucleotides encoding amino acid residues 6 and 8, to expressed the enzyme efficiently in *E. coli*.

In conclusion, DNA and protein of SAK-2 and SAK-1 are not described so that one having skills in the art were convinced that applicants were in possession of the claimed invention at the time the application was filed.

*Response to applicants' traverse*

In response to the rejection under this paragraph of claims 2, 5, 6 and 8-9 applicants explain:

- 1) naturally occurring SAK is protein of 136 amino acids, that is encoded by nucleotide sequence presented in Fig. 4, containing 411 nucleotides including stop codon, and SAK-2 is 132 amino acid long (pages 13 and 14 of REMARKS);
- 2) SEQ ID NO: 9 is 606 nucleotide long and comprises 21 nucleotide long primer sequence on its N terminus followed by 411 nucleotide SAK-1 gene and 174 nucleotide terminator sequence (page 14 of REMARKS).

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Firstly, the explanations applicants offer in the argument should be embedded in the text of the specification.

Secondly, regarding point 1) although SAK is 136 amino acid long, SAK-2 may not be 132 amino acid long because in Fig. 11 it is 5 amino acid shorter than SAK, i.e., it is 131 amino acid long. So what is the correct length of SAK-2 protein?

Regarding point 2) although  $21+411+174=606$ , SAK-1 in Fig. 10 contains after the 21st nt of primer codon ATG. That changes the length of SAK-1 encoding sequence making it 609 nt. So, which length is correct 606 or 609?

In summary, applicants' arguments added new confusions as to the structure of the claimed products.

## Conclusion

Claims 1, 4, 7 and 28 are allowed as directed to the products comprising or consisting of the expression cassette of SEQ ID NO: 1 that is novel. Claims 2, 5-6, 8-9 and 26-27 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached on (571) 272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.  
Art Unit 1652  
Patent Examiner

/Yong D Pak/  
Primary Examiner, Art Unit 1652